MAR 2 7 2012

K120416

Section 5: 510k) Summary

The Summary of Safety and Effectiveness information on the Insulation Tester is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Spectrum Surgical Instruments 4575 Hudson Drive Stow Ohio 44224
Telephone **Facsimile**	330-686-4550 330-686-4555
Date	December 9, 2011
Name	Dennis A. Kovit Director of Operations
Classification	Electrosurgical, cutting and coagulation and accessories.
Predicate:	Jac-Cell Medic K020334
Description:	Insulation Tester

Intended Use	Verify insulation integrity on laparoscopic instruments
Contraindication:	
Warning	Should not be used by or in the presence of someone with an electrical implanted device, such as a pace maker.
Technological Characteristics	This device generates an electrical current and detects the current when there is insufficient insulation covering a laparoscopic instrument.
Performance Testing	In actual test performance, real world conditions were simulated by modifying a laparoscopic shaft to include a small pin hole and also to abrade the surface in an area. These are the two scenarios that would typically be found, however any area not properly insulated would be detected by the insulation tester. A minimum of 30 tests in each condition over 2 different time periods were chosen to be performed in order to assure randomness. 180 tests were completed in all, which was well above the minimum number of verification testing requirements. The insulation tester had a 100% success rate in being able to detect insufficient insulation while not rejected known good insulated laparoscopic shafts.

Substantial Equivalency Information

Measured Values

Conditions / Spectrum Specifications	Spectrum Insulation Tester	Jac-Cell Medic K020334	Comments
Normal (open) Batt. @ 9V – 32 – 40 mA	34.5mA	38.2mA	Spectrum lower = longer Batt. life.
Normal (open) Batt. @ 9V 2200 – 2400 Volts	2.330 Volts	2.374 Volts	Slight voltage diff. performance is same
Normal (open) Batt. @ 7V - 32 – 40 mA	34.5mA	30.9mA	Not at 7V for long period of time. Low Battery.
Normal (open) Batt. @ 7v – 2200 – 2400 Volts	2.330 Volts	2.015 Volts	Spectrum voltage stable 9V through 7V

	Fault (short) Batt. @ 9V – 115 – 145mV	132mA	158mA	Spectrum lower longer Batt. life.
	Fault (short) Batt. @ 7V – 115 – 145 mA	132mA	108mA	Not at 7V for long period of time. Low Battery.
	Fault Detection	Red LED, Sound	Red LED, Sound	Spectrum & Jac-Cell Equal
	Low Battery Indicator	Red LED	Red LED	Spectrum and Jac-Cell Equal
Conclusion	The Spectrum insulation tester is equivalent to the Jac-Cell Medic insulation and continuity tester with respect to insulation testing. Since the Spectrum tester does not test for continuity, no statement can be made in this regard			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spectrum Surgical Instruments, Corporation
% Mr. Dennis A. Kovit
Director of Repair Operations
4575 Hudson Drive
Stow, Ohio 44224-1725

MAR 27 2012

Re: K120416
Trade/Device Name: Insulation Tester
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 1, 2012
Received: March 6, 2012

Dear Mr. Kovit:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Director

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120416

Device Name: Insulation Tester

Indications For Use: The Spectrum Insulation Tester checks for insulation integrity on laparoscopic instruments

Prescription Use ____X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120416